

WHAT IS CLAIMED IS:

1. A nucleic acid construct comprising in operable association a casein gene promoter, a signal sequence and a polynucleotide fragment encoding hirudin.
- 5 2. The nucleic acid construct of Claim 1, wherein the promoter is isolated from a goat β -casein gene.
3. A nucleic acid construct of Claim 1, wherein the polynucleotide fragment has a nucleotide sequence of SEQ ID NO: 15 or 16.
- 10 4. The nucleic acid construct of Claim 1, wherein the signal sequence has a nucleotide sequence of SEQ ID NO: 9.
5. The nucleic acid construct of Claim 1, further comprising one or more β -globin insulator elements.
6. A transgenic non-human mammal whose genome comprises
15 the nucleic acid construct of Claim 1.
7. The transgenic non-human mammal of Claim 6, which is a pig, cattle, horse, goat, camel, sheep or rodent.
8. The transgenic non-human mammal of Claim 6, which is female and can produce milk that contains hirudin encoded by the
20 polynucleotide fragment as defined in Claim 1.
9. The transgenic non-human mammal of Claim 6, which is male and its female offspring whose genome comprises the nucleic acid

construct of Claim 1 can produce hirudin encoded by the polynucleotide fragment as defined in Claim 1.

10. A process for producing hirudin comprising the steps of providing the transgenic non-human mammal of Claim 8, collecting milk
5 from the mammal and recovering hirudin from the milk.

11. A process for producing hirudin comprising the steps of providing a male transgenic non-human mammal of Claim 9, producing female offspring whose genome comprises the nucleic acid construct of Claim 1 from the mammal, collecting milk from the female offspring and
10 recovering hirudin from the milk.

12. An expression vector comprising a replication origin and the nucleic acid construct of Claim 1.

13. The expression vector of Claim 12, wherein the promoter of the nucleic acid construct is isolated from a β -goat casein gene.

15 14. The expression vector of Claim 12, wherein the polynucleotide fragment of the nucleic acid construct has a nucleotide sequence of SEQ ID NO: 15 or 16.

15 15. The expression vector of Claim 12, wherein the signal sequence of the nucleic acid construct has a nucleotide sequence of SEQ
20 ID NO: 9.

16. The expression vector of Claim 12, wherein the nucleic acid construct further comprises one or more β -globin insulator elements.

18. A transformed mammary gland cell comprising the expression

vector of Claim 12.

19. The transformed mammary gland cell of Claim 18, which is derived from human, pig, cattle, horse, goat, camel, sheep or rodent.

20. A mammalian cell isolated from the transgenic non-human transgenic mammal of Claim 6, which comprises a genome comprising the nucleic acid construct of Claim 1.

21. A process for producing hirudin, comprising the steps of culturing the transformed mammary gland cell of Claim 18 under a condition suitable for expressing hirudin and recovering the hirudin therefrom.

22. A process for producing hirudin, comprising the steps of isolating a mammary gland tissue or cell from the transgenic non-human mammal of Claim 6, culturing the isolated mammary gland tissue or cell under a condition suitable for expressing hirudin and recovering the hirudin therefrom.